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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,533	04/02/2001	Michael R. Hufford	IVQ-002	9781
959	7590	02/09/2006	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			GOTTSCALK, MARTIN A	
			ART UNIT	PAPER NUMBER
			3626	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/825,533

Applicant(s)

HUFFORD ET AL.

Examiner

Martin A. Gottschalk

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 31-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 48-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 02 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 01/08/2002.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of claims 4-30 and 48-52 in the reply filed on 11/07/2005 is acknowledged. The traversal is on the ground(s) that there would be no serious burden in examining all of the claims in the application. This is not found persuasive because the original claims are directed to distinct inventions for the reasons given in the requirement for restriction/election, and the search required for each group is not required for the other groups, and they have acquired a separate status in the art because of their recognized divergent subject matter.

The requirement is still deemed proper and is therefore made FINAL.

2. This application contains claims 1-3 and 31-47, drawn to inventions nonelected with traverse in Applicant's communication filed 11/07/2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 21 recites the limitation "...the evaluability database...". There is insufficient antecedent basis for this limitation in the claim. Claim 22 depends from claim 21 and is thus rejected as well. Correction is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 4-30 and 48-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Stark et al (US Pat# 6,827,670, hereinafter, Stark).

A. As per claim 16, Stark discloses a method of predicting subject noncompliance, comprising the steps of:

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(a) providing historical subject compliance data (Stark: col 5, ln 64 to col 6, ln 1; col 7, 57-60; col 11, lns 40-48; Fig. 11, i.e. patient compliance data from the past 10 days is provided to the central computer.);

(b) generating at least one predictive algorithm for predicting subject noncompliance by quantitative analysis of the historical subject compliance data (Stark: col 12, lns 48-63; Fig 14, note the graphic representation which is a type of quantitative analysis.);

(c) translating the at least one predictive algorithm into at least one prediction rule (Stark: col 13, lns 6-16. The Examiner considers that the algorithm is translated it into a rule such as, "If the patient has achieved near 100% performance, then the challenge level of the protocol should be increased".);

(d) obtaining subject compliance information (Stark: col 11, lns 40-48; Fig. 11, i.e. compliance data is obtained from the patient; col 13, lns 2-5, reads on, "...level of average compliance.");

(e) comparing the subject compliance information to the at least one prediction rule to determine if action is needed (Stark: col 5, lns 34-36; col 13, lns 2-5); and

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(f) prompting action if the step of comparing indicates that action is needed  
(Stark: col 13, lns 13-16, reads on "...algorithm increases the challenge level...").

B. As per claims 4-6, 8, 14, 24, and 26, they are rejected for the same reasons as provided above for the corresponding steps of claim 16.

C. As per claim 17, Stark discloses the method of predicting subject noncompliance of claim 16,

wherein said step of providing includes

providing historical protocol data (Stark: col 5, lns 2-4; Fig 9, note that item 107 is labeled "Receive a Protocol" and is connected by arrow 108 coming from the box labeled "Historic Protocols...")

and

wherein said step of generating includes

quantitative analysis of the historical protocol data (Stark: col 7, lns 41-43).

C. As per claims 9 and 25, they are rejected for the same reasons provided above for claim 17.

D. As per claim 18, Stark discloses the method of determining subject noncompliance of claim 17, wherein the step of providing

employs at least one database containing the historical protocol data (Stark: Fig 9, item 36 and the box labeled "Historic Protocols..." which is shown to be receiving input from item 40; Fig 10, item 36).

E. As per claim 10, it is rejected for the same reasons as provided above for claim 18.

F. As per claim 19, Stark discloses the method of predicting subject noncompliance of claim 16, wherein the step of obtaining includes

the use of a portable electronic device capable of displaying information and receiving and storing input from a user (Stark: col 8, lns 12-30).

G. As per claims 7, 11, 15, and 30, they are rejected for the same reasons provided above for claim 19.

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H. As per claims 20-22, Stark discloses the method of predicting subject noncompliance of claim 16, further comprising the step of

(claim 20) creating an evaluability database adapted to store data related to subject compliance;

and

(claim 21) providing access to the evaluability database to a sponsor to allow the sponsor to make a determination regarding a subject based on data from the evaluability database;

and

(claim 22) evaluability database is tailored to a condition affecting the subject (For all three claims, Stark: col 8, lns 57-63, whereby sponsor reads on "treatment professional", and the cited "treatment protocol" is considered to be tailored to a condition affecting the patient. See also col 7, ln 63 to col 8, ln 3).

I. As per claim 23, Stark discloses the method of determining subject noncompliance of claim 16, wherein the step of providing



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employs at least one database containing the historical subject compliance data (Stark: Fig 9, item 36 and box labeled "Historic Protocols..." which is shown to be receiving input from item 40; Fig 10, item 36).

J. As per claim 13, it is rejected for the same reasons as provided above for claim 23.

K. As per claims 27 and 28, Stark discloses the method of enhancing subject compliance of claim 24, wherein the affirmative action includes

(claim 27) reducing

and

(claim 28) increasing

a number of occurrences of the step of obtaining subject compliance information (For both claims, Stark: col 9, ln 67 to col 10, ln 21. The Examiner considers the "...replicate count..." to be a form of compliance information, and notes it is increased following detection that the previous "...effort or angle objective..." was not being achieved. Since the number of occurrences of a replicate would be increased, so would obtaining this

particular form of compliance information. Likewise, if the patient is "...satisfying ahead of schedule, the treatment goal...", logically, the algorithm would move in the opposite direction from the previous example and "...modify the treatment protocol..." such that the "protocol goals may be raised to more challenging levels...". In this scenario, the patient would require an increase in the required effort, and following the logic of the former example, the number of replicates required to comply with the treatment protocol would be reduced.).

N. As per claim 29, Stark discloses the method of enhancing subject compliance of claim 24, wherein the affirmative action includes giving a reward (Stark: col 10, lns 13-23, reads on "...psychological boost...").

O. As per claims 48-52, they are articles of manufacture claims which repeat the same limitations of claims 4, 8, 14, 16, and 24 respectively, the corresponding method claims, as collections of instructions for execution stored on media suitable for use in an electronic device, as opposed to a series of process steps. Since the teachings of Stark disclose the underlying process steps that constitute the method of claims 4, 8, 14, 16, and 24, it is respectfully submitted that they likewise disclose the instructions for executing the steps as well. As such, the limitations of claim 48-52 are rejected for the same reasons given above for claims 4, 8, 14, 16, and 24 respectively.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stark as applied to claim 8 above, and further in view of Smith (Smith, G., "Statistical Reasoning." Third edition. Ch. 15, pgs. 619-667. Allyn and Bacon, a Division of Simon and Schuster, Inc., Needham Heights, MA. 1991, hereinafter Smith.).

A. As per claim 12, Stark suggests the use of statistical analysis and techniques (Stark: col 7, lns 41-48) but fails to explicitly disclose the specific statistical techniques of claim 12.

However, these features are well known in the art as evidenced by the teachings of Smith who discloses the method of determining subject compliance of claim 8, wherein

the step of generating employs at least one of the group of

multiple linear regression (Smith: Ch 15.)

discriminant function analysis,

logistic regression,

neural networks,

classification trees and

regression trees.

It would have been obvious at the time of the invention to one of ordinary skill in the art to incorporate the teachings of Smith within the method of Stark with the motivation of isolating the separate effect of each of several independent variables on a single dependent variable (Smith: pg 620, second paragraph).

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied patent prior art discloses methods,

systems, and algorithms for managing subject compliance (US Pat#s 5,671,734; 5,980,429; 6,171,237; 6,514,200, and PG Pub#s 2003/0178031, 2004/0122701, 2005/0165626). The cited but not applied non-patent literature discloses a Web-based system for managing aspects of clinical trials (Kiuchi et al.).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin A. Gottschalk whose telephone number is (571) 272-7030. The examiner can normally be reached on Mon - Fri 8:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MG  
02/03/2005



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PATENT EXAMINER